(3) *Pyrogens.* Proceed as directed in § 436.32(b) of this chapter, using a solution containing 30 milligrams of erythromycin per milliliter.

(4) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(5) *pH.* Proceed as directed in § 436.202 of this chapter, using a concentration of 50 milligrams of erythromycin per milliliter.

(6) *Residue on ignition.* Proceed as directed in § 436.207(a) of this chapter.

(7) *Heavy metals.* Proceed as directed in § 436.208 of this chapter.

(8) *Identity.* Proceed as directed in § 436.211 of this chapter, using the sample preparation method described in paragraph (b)(3) of that section.

[51 FR 35215, Oct. 2, 1986, as amended at 55 FR 11584, Mar. 29, 1990]

§ 452.35 Erythromycin stearate.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin stearate is the odorless, white or slightly yellow powder of the stearic acid salt of erythromycin. It is practically insoluble in water but is soluble in alcohol, methyl alcohol, chloroform, and ether. It is so purified and dried that:

(i) It contains not less than 550 micrograms of erythromycin per milligram, calculated on an anhydrous basis.

(ii) [Reserved]

(iii) Its moisture content is not more than 4.0 percent.

(iv) Its pH is not less than 6.0 and not more than 11.0.

(v) Its residue on ignition is not more than 1.0 percent.

(vi) It gives positive identity tests for erythromycin stearate.

(vii) It is crystalline.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, moisture, pH residue on ignition, identity, and crystallinity.

(ii) Samples required: A minimum of 10 containers, each consisting of 500 milligrams.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed sample in sufficient methyl alcohol to give a concentration of 1 milligram of erythromycin base per milliliter (estimated). Further dilute with 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to the reference concentration of 1.0 microgram of erythromycin base per milliliter (estimated).

(2) [Reserved]

(3) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(4) *pH.* Proceed as directed in § 436.202 of this chapter, using a 1 percent slurry of erythromycin stearate in water.

(5) *Residue on ignition.* Proceed as directed in § 436.207(a) of this chapter.

(6) *Identity.* Proceed as directed in § 436.211 of this chapter, using the sample preparation method described in paragraph (b)(2) of that section.

(7) *Crystallinity.* Proceed as directed in § 436.203(a) of this chapter.

[39 FR 19149, May 30, 1974, as amended at 50 FR 19920, 19921, May 13, 1985]

§ 452.50 Clarithromycin.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Clarithromycin is 6-O-methylerythromycin A. It is so purified and dried that:

(i) Its potency is not less than 960 micrograms of clarithromycin activity per milligram, on an anhydrous basis.

(ii) Its moisture content is not more than 2.0 percent.

(iii) The pH of a 0.2 percent (weight per volume) slurry in aqueous methanol (95:5) is not less than 7.5 and not more than 10.0.

(iv) Its residue on ignition is not more than 0.3 percent.

(v) Its heavy metals content is not more than 20 parts per million.

(vi) Its specific rotation in chloroform containing 10 milligrams of clarithromycin per milliliter at 20 °C is between -89° and -95°, calculated on an anhydrous basis.

(vii) It gives a positive identity test.

(viii) It is crystalline.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.